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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,891	11/13/2003	Kazuo Nishimura	02015D/HG	1113
1933	7590	01/04/2005	EXAMINER	
FRISHAUF, HOLTZ, GOODMAN & CHICK, PC 767 THIRD AVENUE 25TH FLOOR NEW YORK, NY 10017-2023			HABTE, KAHSAI	
			ART UNIT	PAPER NUMBER
			1624	

DATE MAILED: 01/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/713,891

Applicant(s)

NISHIMURA ET AL.

Examiner

Kahsay Habte, Ph. D.

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 10/031,540.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/13/2003</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

1. Claims 1-14 are pending in this application.

Information Disclosure Statement

2. Applicant's Information Disclosure Statement, filed 11/13/2003 has been acknowledged. Please refer to Applicant's copies of the 1449 submitted herewith.

Specification

3. The specification is objected because the status of the application 10/031,540, to which applicant claims priority in the 1st paragraph of the specification is not updated. The status of nonprovisional parent application(s) (whether patented or abandoned) to which applicants claim domestic priority should be included. If a parent application has become a patent, the expression "now Patent No. 6,713,472" should follow the filing date of the parent application.

Note that this application is a divisional of 10/031,540 filed on 01/18/2002 (US Pat. No. 6,713,472) which is a 371 of PCT/JP00/04964 filed on 07/26/2000.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1624

Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

a. In claims 1 and 10, the phrases “R⁶ is hydrogen, lower alkyl, cycloalkyl, hydroxy, lower alkoxy, aryl, aryloxy or an aromatic heterocycle”, “n is 0 or 1” and “A₂ is carbonyl or sulfonyl” are not clear. There are no variables “R⁶”, “n” or “A₂” in the chemical structure or in any of the definitions for the substituents of the thiazine ring. It is recommended that applicants delete said phrases, because while said variables belong to the definition of “X is R⁶-(A₂)_n-N” in the parent case (10/031,540), they are not present in the claimed compounds.

Note that claim 3 recites “n is 1” and claim 4 recites “R⁶ is lower alkyl...” and should be deleted for the reason given above. It is also required that applicants delete the definition of “R⁶” from claim 5.

b. In claim 11, the phrase “a method of inhibiting chymase in a patient comprising administering to a patient in need thereof” is not clear. How can one skilled in the art tell exactly who is and who is not in need thereof? For example, one skilled knows that Alzheimer’s patients need acetylcholinesterase inhibitors, but it is unclear who is in need of chymase inhibitors.

According to an abstract from a review article {Takai S, Jin D, and Miyazaki M., *Nippon Yakurigaku Zasshi*, 1999 Oct; 114 Suppl 1:41p-47P (Article in Japanese)}, it has

Art Unit: 1624

been noted on lines 1-3 "Human chymase forms angiotensin (ANG) I to ANG II, whereas the roles of ANG II generated by chymase and the effects of chymase inhibitors have been unclear." This indicates that the role of chymases is not clear to one skilled in the art, thus it is not clear which diseases are associated with chymase and which diseases are not.

It is recommended that applicants amend the claim by reciting specific diseases (e.g. cardiac infraction, heart failure) from the specification as it was done in SN 10/031,540.

Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kahsay Habte, Ph. D. whose telephone number is (571) 272-0667. The examiner can normally be reached on M-F (9.00AM- 5:30PM).


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on (571) 272-0674, if there is no reply within 24 hours, James Wilson (Acting SPE) can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Art Unit: 1624

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kalsay Habte, Ph. D.
Patent Examiner
Art Unit 1624

KH
January 3, 2005